

108TH CONGRESS
1ST SESSION

S. 51

To provide access and choice for use of generic drugs instead of nongeneric drugs under Federal health care programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 7, 2003

Mr. JOHNSON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide access and choice for use of generic drugs instead of nongeneric drugs under Federal health care programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Generic Pharmaceutical Access and Choice for Con-
6 sumers Act of 2003”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

TITLE I—REQUIRING THE USE OF GENERIC DRUGS

- Sec. 101. Requiring the use of generic drugs under the Public Health Service Act.
- Sec. 102. Application to Federal employees health benefits program.
- Sec. 103. Application to medicare program.
- Sec. 104. Application to medicaid program.
- Sec. 105. Application to Indian Health Service.
- Sec. 106. Application to veterans programs.
- Sec. 107. Application to recipients of uniformed services health care.
- Sec. 108. Application to Federal prisoners.

TITLE II—THERAPEUTIC EQUIVALENCE REQUIREMENTS FOR
GENERIC DRUGS

- Sec. 201. Therapeutic equivalence of generic drugs.

TITLE III—GENERIC PHARMACEUTICALS AND MEDICARE
REFORM

- Sec. 301. Sense of the Senate on requiring the use of generic pharmaceuticals under the medicare program.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) Generic pharmaceuticals are approved by
5 the Food and Drug Administration on the basis of
6 scientific testing and other information establishing
7 that such pharmaceuticals are therapeutically equiv-
8 alent to brand-name pharmaceuticals, ensuring con-
9 sumers a safe, efficacious, and cost-effective alter-
10 native to brand-name innovator pharmaceuticals.

11 (2) The pharmaceutical market has become in-
12 creasingly competitive during the last decade be-
13 cause of the increasing availability and accessibility
14 of generic pharmaceuticals.

15 (3) The Congressional Budget Office estimates
16 that—

1 (A) the substitution of generic pharma-
2 ceuticals for brand-name pharmaceuticals will
3 save purchasers of pharmaceuticals between
4 \$8,000,000,000 and \$10,000,000,000 each
5 year; and

6 (B) quality generic pharmaceuticals cost
7 between 25 percent and 60 percent less than
8 brand-name pharmaceuticals, resulting in an es-
9 timated average savings of \$15 to \$30 on each
10 prescription filled.

11 (4) Independent studies have estimated that
12 generics provide an average savings of \$45.50 for
13 each prescription drug sold.

14 (5) Generic pharmaceuticals are widely accepted
15 by both consumers and the medical profession, as
16 the market share held by generic pharmaceuticals
17 compared to brand-name pharmaceuticals has more
18 than doubled during the last decade, from approxi-
19 mately 19 percent to 43 percent, according to the
20 Congressional Budget Office.

21 (6) Generic pharmaceuticals can save con-
22 sumers an additional \$1,320,000,000 each year for
23 each 1 percent increase in the use of such pharma-
24 ceuticals.

1 (7) Generic pharmaceutical use can help both
2 consumers and the Government reduce the cost of
3 prescription drugs.

4 (b) PURPOSES.—The purposes of this Act are—

5 (1) to reduce the cost of prescription drugs to
6 the United States Government and to beneficiaries
7 under Federal health care programs while maintain-
8 ing the quality of health care by requiring the use
9 of generic drugs rather than nongeneric drugs, un-
10 less no therapeutically equivalent generic drug has
11 been approved under the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 301 et seq.) or the non-
13 generic drug is specifically—

14 (A) ordered by the prescribing provider; or

15 (B) requested by the individual for whom
16 the drug is prescribed; and

17 (2) to increase the utilization of generic phar-
18 maceuticals by requiring the Food and Drug Admin-
19 istration, where appropriate, to determine that a ge-
20 neric pharmaceutical is the therapeutic equivalent of
21 its brand-name counterpart, and by affording na-
22 tional uniformity to that determination.

1 **TITLE I—REQUIRING THE USE**
 2 **OF GENERIC DRUGS**

3 **SEC. 101. REQUIRING THE USE OF GENERIC DRUGS UNDER**
 4 **THE PUBLIC HEALTH SERVICE ACT.**

5 (a) IN GENERAL.—Part B of title II of the Public
 6 Health Service Act (42 U.S.C. 238 et seq.) is amended
 7 by adding at the end the following new section:

8 **“SEC. 249. USE OF GENERIC DRUGS REQUIRED.**

9 “(a) REQUIREMENT.—Each grant or contract en-
 10 tered into under this Act that involves the provision of
 11 health care items or services to individuals shall include
 12 provisions to ensure that any prescription drug provided
 13 for under such grant or contract is filled by providing the
 14 generic form of the drug involved, unless no generic form
 15 of the drug has been approved under the Federal Food,
 16 Drug, and Cosmetic Act or the nongeneric form of the
 17 drug is specifically—

18 “(1) ordered by the prescribing provider; or

19 “(2) requested by the individual for whom the
 20 drug is prescribed.

21 “(b) DEFINITIONS.—In this section:

22 “(1) GENERIC FORM OF THE DRUG.—The term
 23 ‘generic form of the drug’ means a drug that is the
 24 subject of an application approved under subsection
 25 (b)(2) or (j) of section 505 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355), for which
2 the Secretary has made a determination that the
3 drug is the therapeutic equivalent of a listed drug
4 under section 505(o) of that Act (21 U.S.C. 355(o)).

5 “(2) NONGENERIC FORM OF THE DRUG.—The
6 term ‘nongeneric form of the drug’ means a drug
7 that is the subject of an application approved
8 under—

9 “(A) section 505(b)(1) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C.
11 355(b)(1)); or

12 “(B) section 505(b)(2) of such Act and
13 that has been determined to be not therapeuti-
14 cally equivalent to any listed drug.

15 “(3) PRESCRIPTION DRUG.—The term ‘pre-
16 scription drug’ means a drug that is subject to the
17 provisions of section 503(b) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 353(b)).”.

19 (b) EFFECTIVE DATE.—The amendment made by
20 this section shall apply with respect to any drug furnished
21 on or after the date of enactment of this Act.

1 **SEC. 102. APPLICATION TO FEDERAL EMPLOYEES HEALTH**
 2 **BENEFITS PROGRAM.**

3 (a) IN GENERAL.—Section 8902 of title 5, United
 4 States Code, is amended by adding at the end the fol-
 5 lowing new subsection:

6 “(p) If a contract under this chapter provides for the
 7 provision of, the payment for, or the reimbursement of the
 8 cost of any prescription drug (as defined in paragraph (3)
 9 of section 249(b) of the Public Health Service Act), the
 10 carrier shall provide, pay, or reimburse the cost of the ge-
 11 neric form of the drug (as defined in paragraph (1) of
 12 such section), except that this subsection shall not apply
 13 if the nongeneric form of the drug (as defined in para-
 14 graph (2) of such section) is specifically—

15 “(1) ordered by the prescribing provider; or

16 “(2) requested by the individual for whom the
 17 drug is prescribed.”.

18 (b) EFFECTIVE DATE.—The amendment made by
 19 this section shall apply to any prescription drug furnished
 20 during contract years beginning on or after January 1,
 21 2004.

22 **SEC. 103. APPLICATION TO MEDICARE PROGRAM.**

23 (a) IN GENERAL.—Section 1861(t) of the Social Se-
 24 curity Act (42 U.S.C. 1395x(t)) is amended by adding at
 25 the end the following new paragraph:

1 “(3) For purposes of paragraph (1), the term ‘drugs’
 2 means the generic form of the drug (as defined in section
 3 249(b)(1) of the Public Health Service Act), unless no ge-
 4 neric form of the drug has been approved under the Fed-
 5 eral Food, Drug, and Cosmetic Act or the nongeneric form
 6 of such drug (as defined in section 249(b)(2) of such Act)
 7 is specifically—

8 “(A) ordered by the health care provider; or

9 “(B) requested by the individual to whom the
 10 drug is provided.”.

11 (b) EFFECTIVE DATE.—

12 (1) IN GENERAL.—Except as provided in para-
 13 graph (2), the amendment made by this section shall
 14 apply with respect to any prescription drug fur-
 15 nished on or after the date of enactment of this Act.

16 (2) MEDICARE+CHOICE PLANS.—In the case of
 17 a Medicare+Choice plan offered by a
 18 Medicare+Choice organization under part C of title
 19 XVIII of the Social Security Act (42 U.S.C. 1395w-
 20 21 et seq.), the amendment made by this section
 21 shall apply to any prescription drug furnished dur-
 22 ing contract years beginning on or after January 1,
 23 2004.

1 **SEC. 104. APPLICATION TO MEDICAID PROGRAM.**

2 (a) IN GENERAL.—Section 1902(a) of the Social Se-
3 curity Act (42 U.S.C. 1396a(a)) is amended—

4 (1) in paragraph (64), by striking “and” at the
5 end;

6 (2) in paragraph (65), by striking the period at
7 the end and inserting “; and”; and

8 (3) by adding the following new paragraph:

9 “(66) provide that the State shall, in conjunc-
10 tion with the program established under section
11 1927(g), provide for the use of a generic form of a
12 drug (as defined in paragraph (1) of section 249(b)
13 of the Public Health Service Act), unless no generic
14 form of the drug has been approved under the Fed-
15 eral Food, Drug, and Cosmetic Act or the non-
16 generic form of the drug (as defined in paragraph
17 (2) of such section) is specifically—

18 “(A) ordered by the provider; or

19 “(B) requested by the individual to whom
20 the drug is provided.”.

21 (b) EFFECTIVE DATE.—The amendment made by
22 this section shall apply with respect to any prescription
23 drug furnished under State plans that are approved or re-
24 newed on or after the date of enactment of this Act.

1 **SEC. 105. APPLICATION TO INDIAN HEALTH SERVICE.**

2 (a) IN GENERAL.—Title II of the Indian Health Care
3 Improvement Act (25 U.S.C. 1621 et seq.) is amended—

4 (1) by redesignating sections 224 and 225 as
5 sections 225 and 226, respectively; and

6 (2) by inserting after section 223 the following
7 new section:

8 **“SEC. 224. USE OF GENERIC DRUGS REQUIRED.**

9 “In providing health care items or services under this
10 Act, the Indian Health Service shall ensure that any pre-
11 scription drug (as defined in paragraph (3) of section
12 249(b) of the Public Health Service Act) that is provided
13 under this Act is the generic form of the drug (as defined
14 in paragraph (1) of such section) involved, unless no ge-
15 neric form of the drug has been approved under the Fed-
16 eral Food, Drug, and Cosmetic Act or the nongeneric form
17 of the drug (as defined in paragraph (2) of such section)
18 is specifically—

19 “(1) ordered by the prescribing provider; or

20 “(2) requested by the individual for whom the
21 drug is prescribed.”.

22 (b) EFFECTIVE DATE.—The amendment made by
23 this section shall apply with respect to any prescription
24 drug furnished on or after the date of enactment of this
25 Act.

1 **SEC. 106. APPLICATION TO VETERANS PROGRAMS.**

2 (a) USE OF GENERIC DRUGS REQUIRED.—Sub-
 3 chapter III of chapter 17 of title 38, United States Code,
 4 is amended by inserting after section 1722A the following
 5 new section:

6 **“§ 1722B. Use of generic drugs required**

7 “When furnishing a prescription drug (as defined in
 8 paragraph (3) of section 249(b) of the Public Health Serv-
 9 ice Act) under this chapter, the Secretary shall furnish
 10 a generic form of the drug (as defined in paragraph (1)
 11 of such section), unless no generic form of the drug has
 12 been approved under the Federal Food, Drug, and Cos-
 13 metic Act or the nongeneric form of the drug (as defined
 14 in paragraph (2) of such section) is specifically—

15 “(1) ordered by the prescribing provider; or

16 “(2) requested by the individual for whom the
 17 drug is prescribed.”.

18 (b) CLERICAL AMENDMENT.—The table of sections
 19 at the beginning of chapter 17 of such title is amended
 20 by inserting after the item relating to section 1722A the
 21 following new item:

“1722B. Use of generic drugs required.”.

22 (c) EFFECTIVE DATE.—The amendments made by
 23 this section shall apply with respect to any prescription
 24 drug furnished on or after the date of enactment of this
 25 Act.

1 **SEC. 107. APPLICATION TO RECIPIENTS OF UNIFORMED**
 2 **SERVICES HEALTH CARE.**

3 (a) USE OF GENERIC DRUGS REQUIRED.—Chapter
 4 55 of title 10, United States Code, is amended by adding
 5 at the end the following new section:

6 **“§ 1111. Use of generic drugs required**

7 “The Secretary of Defense shall ensure that each
 8 health care provider who furnishes a prescription drug (as
 9 defined in paragraph (3) of section 249(b) of the Public
 10 Health Service Act) furnishes the generic form of the drug
 11 (as defined in paragraph (1) of such section), unless no
 12 generic form of the drug has been approved under the
 13 Federal Food, Drug, and Cosmetic Act or the nongeneric
 14 form of the drug (as defined in paragraph (2) of such sec-
 15 tion) is specifically—

16 “(1) ordered by the prescribing provider; or

17 “(2) requested by the individual for whom the
 18 drug is prescribed.”.

19 (b) CLERICAL AMENDMENT.—The table of sections
 20 at the beginning of such chapter is amended by inserting
 21 after the item relating to section 1110 the following new
 22 item:

“1111. Use of generic drugs required.”.

23 (c) EFFECTIVE DATE.—The amendments made by
 24 this section shall apply with respect to any drug furnished
 25 on or after the date of enactment of this Act.

1 **SEC. 108. APPLICATION TO FEDERAL PRISONERS.**

2 (a) IN GENERAL.—Section 4006(b) of title 18,
3 United States Code, is amended by adding at the end the
4 following new paragraph:

5 “(3) USE OF GENERIC DRUGS REQUIRED.—The
6 Attorney General shall ensure that each health care
7 provider who furnishes a prescription drug (as de-
8 fined in paragraph (3) of section 249(b) of the Pub-
9 lic Health Service Act) to a prisoner charged with or
10 convicted of an offense against the United States
11 furnishes the generic form of the drug (as defined
12 in paragraph (1) of such section), unless no generic
13 form of the drug has been approved under the Fed-
14 eral Food, Drug, and Cosmetic Act or the non-
15 generic form of the drug (as defined in paragraph
16 (2) of such section) is specifically—

17 “(A) ordered by the prescribing provider;
18 or

19 “(B) requested by the prisoner for whom
20 the drug is prescribed.”.

21 (b) EFFECTIVE DATE.—The amendment made by
22 this section shall apply with respect to any prescription
23 drug furnished on or after the date of enactment of this
24 Act.

1 **TITLE** **II—THERAPEUTIC**
2 **EQUIVALENCE** **REQUIRE-**
3 **MENTS FOR GENERIC DRUGS**

4 **SEC. 201. THERAPEUTIC EQUIVALENCE OF GENERIC**
5 **DRUGS.**

6 (a) IN GENERAL.—Section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

8 (1) by adding at the end the following new sub-
9 section:

10 “(o)(1) For each application filed under subsection
11 (b)(2) or subsection (j), the Secretary shall determine
12 whether the drug for which the application is filed is the
13 therapeutic equivalent of the drug for which the investiga-
14 tions have been made under subsection (b)(1)(A) (in this
15 subsection referred to as the ‘reference drug’) or the listed
16 drug referred to in subsection (j)(2)(A)(i). For applica-
17 tions approved after the date of enactment of this sub-
18 section, the Secretary’s determination shall be made be-
19 fore the approval of the application. For such applications
20 approved before such date, the most recent determination
21 made by the Secretary shall be confirmed.

22 “(2) For purposes of paragraph (1), a drug is the
23 therapeutic equivalent of a reference drug or a listed drug
24 if—

1 “(A) each active ingredient of the drug and ei-
2 ther the reference drug or the listed drug is the
3 same;

4 “(B) the drug and either the reference drug or
5 the listed drug—

6 “(i) are of the same dosage form;

7 “(ii) have the same route of administra-
8 tion;

9 “(iii) are identical in strength or con-
10 centration; and

11 “(iv) are expected to have the same clinical
12 effect and safety profile when administered to
13 patients under conditions specified in the label-
14 ing; and

15 “(C) the drug does not present a known bio-
16 equivalence problem, or if the drug presents such a
17 problem, the drug is shown to meet an appropriate
18 bioequivalence standard.

19 “(3) With respect to a drug for which a therapeutic
20 equivalence determination has been made or confirmed
21 under this subsection, no State or political subdivision of
22 a State may establish or continue in effect with respect
23 to therapeutic equivalence of the drug to either a reference
24 drug or a listed drug, any requirement which is different
25 from, or in addition to, or is otherwise not identical with,

1 the Secretary's determination or confirmation under this
 2 subsection.”; and

3 (2) in subsection (j)(7)(A), by adding at the
 4 end the following new clause:

5 “(iv) The Secretary shall include in each revi-
 6 sion of the list under clause (ii) on or after the date
 7 of enactment of this clause the official and propri-
 8 etary name of each reference drug or listed drug
 9 that is therapeutically equivalent to a drug approved
 10 under subsection (b)(2) or under this subsection
 11 during the preceding 30-day period, as determined
 12 under subsection (o).”.

13 (b) EFFECTIVE DATE.—The amendments made by
 14 this section shall take effect on the date of enactment of
 15 this Act.

16 **TITLE III—GENERIC PHARMA-** 17 **CEUTICALS AND MEDICARE** 18 **REFORM**

19 **SEC. 301. SENSE OF THE SENATE ON REQUIRING THE USE** 20 **OF GENERIC PHARMACEUTICALS UNDER THE** 21 **MEDICARE PROGRAM.**

22 It is the sense of the Senate that legislative language
 23 requiring the safe and cost-effective use of generic phar-
 24 maceuticals should be considered in conjunction with any
 25 legislation that adds a comprehensive prescription drug

- 1 benefit to the medicare program under title XVIII of the
- 2 Social Security Act (42 U.S.C. 1395 et seq.).

